CLAIMS

1. A capsule comprising a tablet, granule or fine granule wherein the release of active ingredient is controlled and a gel-forming polymer.

2. The capsule according to claim 1, wherein the release of active ingredient is controlled by a release-controlled coating-layer formed on a core particle containing an active ingredient.

3. The capsule according to claim 2, wherein the release-controlled coating-layer contains a pH-dependently soluble polymer.

4. The capsule according to claim 2, wherein the release-controlled coating-layer is a diffusion-controlled layer.

5. The capsule according to claim 1, wherein the release of active ingredient is controlled by dispersing an active ingredient into a release-controlled matrix composing tablet, granule or fine granule.

6. The capsule according to claim 3 or 4, wherein the tablet, granule or fine granule in which the release of active ingredient is controlled has a disintegrant layer containing disintegrant formed on the core particle containing an active ingredient and a release-controlled coating-layer formed on said disintegrant layer, and the

release of active ingredient is initiated after a certain lag time.

7. The capsule according to any one of claims 3 to 6, wherein the tablet, granule or fine granule in which the release of active ingredient is controlled is coated with a gel-forming polymer.

8. The capsule according to claim 7 which further contains a gel-forming polymer.

9. The capsule according to any one of claims 1 to 7, which comprises two kinds of tablet, granule or fine granule having different release properties of active ingredient.

10. The capsule according to claim 9, which comprises a tablet, granule or fine granule having an enteric coat that releases an active ingredient at the pH of about 5.5 and a tablet, granule or fine granule having a release-controlled coating-layer that releases an active ingredient at the pH of about 6.0 or above.

11. The capsule according to claim 1, 7 or 8, wherein the gel-forming polymer is a polymer whose viscosity of 5% aqueous solution is about 3,000 mPa·s or more at 25°C.

12. The capsule according to claim 1, 7 or 8, wherein the gel-forming polymer is a polymer having molecular weight of 400,000 to 10,000,000.

13. The capsule according to any one of claims 2 to 4

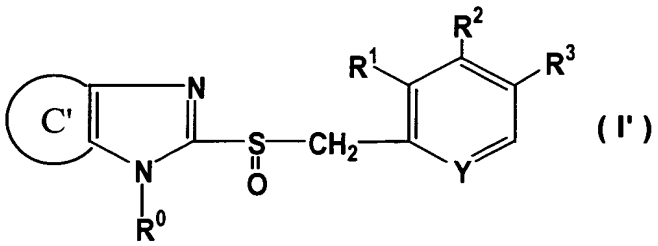
or 6, wherein the release-controlled coating-layer is a layer containing one or more kinds of polymeric substances selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, ethyl acrylate-methyl methacrylate-trimethylammoniumethyl methacrylate chloride copolymer, methyl methacrylate-ethyl acrylate copolymer, methacrylic acid-methyl acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate and polyvinyl acetate phthalate.

14. The capsule according to claim 13, wherein the release-controlled coating-layer is comprised of 2 or more kinds of layers.

15. The capsule according to claim 1, wherein the release-controlled granule or fine granule has a particle size of about 100-1,500 μm.

16. The capsule according to claim 1, wherein the active ingredient is a proton pump inhibitor (PPI).

17. The capsule according to claim 16, wherein the PPI is an imidazole compound represented by the formula (I'):



(I')

wherein ring C' is an optionally substituted benzene ring or an optionally substituted aromatic monocyclic heterocyclic ring, R^0 is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group, R^1, R^2 and R^3 are the same or different and are a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, and Y represents a nitrogen atom or CH; or a salt thereof or an optically active isomer thereof.

18. The capsule according to claim 17, wherein the imidazole compound is lansoprazole.

19. The capsule according to claim 17, wherein PPI is an optically active R-isomer of lansoprazole.

20. The capsule according to any one of claim 1, 7 or 8, wherein the gel-forming polymer is one or more kinds of substances selected from the group consisting of polyethylene oxide (PEO, molecular weight: 400,000-10,000,000), hydroxypropylmethyl cellulose (HPMC), carboxymethyl cellulose (CMC-Na), hydroxypropyl cellulose (HPC), hydroxyethyl cellulose and carboxyvinyl polymer.

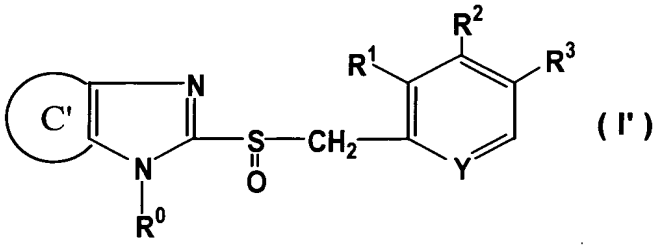
21. The capsule according to any one of claim 1, 7 or

8, wherein the gel-forming polymer is polyethylene oxide (molecular weight: 400,000-10,000,000).

22. The capsule according to claim 1 or 8, wherein the gel-forming polymer is added as a powder, fine granule or granule.

23. The capsule according to claim 3, wherein the pH-dependently soluble polymer is methyl methacrylate-methacrylic acid copolymer.

24. A tablet, granule or fine granule wherein the release of active ingredient is controlled, said tablet, granule or fine granule comprising a core particle containing an imidazole compound represented by the formula (I'):



(I')

wherein ring C' is an optionally substituted benzene ring or an optionally substituted aromatic monocyclic heterocyclic ring, R^0 is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group, R^1, R^2 and R^3 are the same or different and are a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, and Y represents a nitrogen atom or CH; or a salt

thereof or an optically active isomer thereof as an active ingredient, and

a pH-dependently soluble release-controlled coating-layer which comprises one kind of polymeric substance or a mixture of two or more kinds of polymeric substances having different release properties selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, methacrylic acid-methyl acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate, polyvinyl acetate phthalate and shellac, and said polymeric substance is soluble in the pH range of 6.0 to 7.5 .

25. The tablet, granule or fine granule according to claim 24, wherein the pH-dependently soluble release-controlled coating-layer is formed on an intermediate layer which is formed on a core particle.

26. The capsule comprising the tablet, granule or fine granule according to claim 24.

27. The capsule comprising the tablet, granule or fine granule according to claim 24 and an enteric-coated tablet, granule or fine granule containing a compound represented by the formula (I').

28. The tablet, granule or fine granule according to

claim 24, wherein the active ingredient is lansoprazole.

29. The tablet, granule or fine granule according to claim 24, wherein the active ingredient is an optically active R-isomer of lansoprazole.

30. The tablet, granule or fine granule according to claim 24, wherein the active ingredient is an optically active S-isomer of lansoprazole.

31. The tablet, granule or fine granule according to claim 24, wherein the active ingredient is a derivative of lansoprazole.

32. The tablet, granule or fine granule according to claim 24, wherein the active ingredient is a derivative of optically active R-isomer of lansoprazole.

33. The tablet, granule or fine granule according to any one of claim 24, 25 or 28 to 32, comprising having an enteric coat on the core particle containing an active ingredient, a disintegrant layer containing disintegrant on said enteric coat and a release-controlled coating-layer on said disintegrant layer.

34. The tablet, granule or fine granule according to any one of claim 28 to 33, which is coated with a gel-forming polymer.

35. An extended release capsule comprising the tablet, granule or fine granule according to any one of claim 28 to 32 and a gel-forming polymer.

36. A tablet, granule or fine granule according to claim 24 wherein the release of active ingredient is controlled by two or more kinds of release-controlled coating-layers, and the outermost release-controlled coating-layer is soluble at higher pH than the inner release-controlled coating-layer.

37. The tablet, granule or fine granule according to claim 36, wherein the inner release-controlled coating-layer is soluble in the pH range of 6.0-7.0 and the outermost release-controlled coating-layer is soluble at the pH of 7.0 or above.

38. The tablet, granule or fine granule according to claim 36, wherein the inner release-controlled coating-layer is soluble in the pH range of 6.5-7.0 and the outermost release-controlled coating-layer is soluble at the pH of 7.0 or above.

39. The tablet, granule or fine granule according to claim 36, wherein the thickness of the outermost release-controlled coating-layer is 100 μm or less.

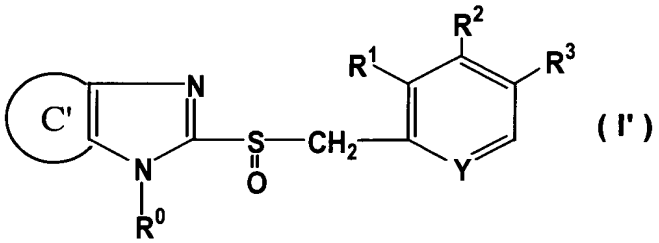
40. The granule or fine granule according to claim 36, wherein the release-controlled granule or fine granule has a particle size of about 100-1,500 μm.

41. A capsule comprising

(i) a tablet, granule or fine granule in which the release of active ingredient is controlled; said tablet, granule or

fine granule comprises

a core particle containing an imidazole compound represented by the formula (I'):



(I')

wherein ring C' is an optionally substituted benzene ring or an optionally substituted aromatic monocyclic heterocyclic ring, R^0 is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group, R^1, R^2 and R^3 are the same or different and are a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, and Y represents a nitrogen atom or CH; or a salt thereof or an optically active isomer thereof as an active ingredient, and

a pH-dependently soluble release-controlled coating-layer which comprises one kind of polymeric substance or a mixture of two or more kinds of polymeric substances having different release properties selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, methacrylic acid-methyl

acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate, polyvinyl acetate phthalate and shellac; said polymeric substance is soluble in the pH range of 6.0 to 7.5, and

(ii) a tablet, granule or fine granule comprising a core particle containing an active ingredient and enteric coat which is dissolved, thereby an active ingredient being released in the pH range of no less than 5.0, nor more than 6.0.

42. The capsule according to claim 41, wherein the pH-dependently soluble release-controlled coating-layer is formed on an intermediate layer which is formed on the core particle containing an active ingredient.

43. The capsule according to claim 41, wherein the active ingredient is lansoprazole.

44. The capsule according to claim 41, wherein the active ingredient is an optically active R-isomer of lansoprazole.

45. The capsule according to claim 41, wherein the active ingredient is an optically active S-isomer of lansoprazole.

46. The capsule according to claim 41, wherein the core particle containing an active ingredient contains a stabilizer of basic inorganic salt.

47. The capsule according to claim 41, wherein the

pH-dependently soluble release-controlled coating-layer of the tablet, granule or fine granule in which the release of an active ingredient is controlled is a layer soluble in the pH range of no less than 6.5, nor more than 7.0.

48. The capsule according to claim 47, wherein the pH-dependently soluble release-controlled coating-layer contains a mixture of two or more kinds of methyl methacrylate-methacrylic acid copolymers having different release properties.

49. The capsule according to claim 41, which further contains a gel-forming polymer.